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Dated: July 10, 2009
Electronic Signature for Megan E. Williams: /Megan E. Williams/

Docket No.: BGG-A117CNRCE2
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Michele Sanicola-Nadel *et al.*

Patent No.: 7,531,174

Application No.: 10/693,538

Confirmation No.: 4018

Filed: October 23, 2003

Art Unit: 1643

For: **CRIPTO BLOCKING ANTIBODIES AND
USES THEREOF**

Examiner: Huff, Sheela J.

MS Patent Extension
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT UNDER 37 CFR § 1.702(b)(2)

Dear Sir:

1. This statement is respectfully submitted in support of the “Application for Patent Term Adjustment Including Request for Reconsideration Under 37 CFR §1.705(b) and (d)” for the above-referenced patent. In view of the following, it is respectfully requested that Patentees be granted a patent term adjustment of **531 days** for the above-referenced application.
2. The patent term adjustment per the “Determination of Patent Term Adjustment Under 35 U.S.C. §154(b)” as shown on the face of the issued patent is 233 days. This determination of 233 days is in error for the reasons discussed below.
3. The factual bases for the above adjustment are set forth as follows:

A. Examination Delays Pursuant to 37 CFR §1.702 and §1.703

Pursuant to 37 CFR §1.703(f), the period of adjustment of the term of the patent under §1.702 is the sum of the periods of examination delay calculated under subparagraphs (a)-(e), to the extent that such periods are not overlapping, less the sum of the periods calculated under §1.704 (the period of Applicant Delay). In the above-referenced patent, Patentees are entitled to

a period of examination delay equal to the sum of the periods of delay under §1.703(a) and (b) for the reasons set forth below.

(i) “14 Month Delay” Pursuant to §1.703(a)(1)

In accordance 37 CFR §1.703(a)(1), Patentees are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. §132 not later than 14 months after the actual filing date (*i.e.*, by December 23, 2004). As shown in the USPTO’s Patent Term Adjustment Calculation Sheet (Exhibit A), the Office failed to mail an action under 35 U.S.C. §132 (a Restriction Requirement) until October 18, 2005. As such, Patentees are entitled to a period of patent term adjustment beginning December 24, 2004 and ending on October 18, 2005, the date of mailing of the Restriction Requirement by the Office. Accordingly, the period of patent term adjustment due to the 14 Month Delay by the Office is **299 days**. This is consistent with the PTA Calculation Sheet (Exhibit A) from the Office.

(ii) “Three Years Delay” Pursuant to 37 CFR §1.703(b)

Patentees respectfully submit that the Office did not comply with the requirement of 35 U.S.C. §154(b) and 37 CFR §1.702(b), which requires issuance of a patent within 3 years after the date on which the patent was filed under 35 U.S.C. §111(a). As indicated on the face of the patent, the instant patent issued on May 12, 2009. As such, there was a delay of 932 days.

However, since the exclusionary period for continued examination set forth in 37 CFR §1.702(b)(1) applies to the instant patent, the number of days in the period beginning on the date on which Patentees first filed a Request for Continued Examination (November 8, 2007) and ending on the issue date of the patent (May 12, 2009), *i.e.*, 552 days, is excluded from the period of Three Years Delay (*i.e.*, 932 days). Therefore, in accordance with 37 CFR §1.703, Patentees have calculated a maximum period of Three Years Delay based on the period of time beginning on the day after the date that is three years after the date on which the above-referenced patent was filed under 35 U.S.C. § 111(a) (*i.e.*, October 24, 2006), and ending on the date Patentees first filed a Request for Continued Examination (*i.e.*, November 8, 2007). This period of delay is **380 days**.

(iii) “4 Month PTO Issue of Patent Delay” Pursuant to 37 CFR § 1.702(a)(4)

The Office did not comply with the requirement of 37 CFR § 1.702(a)(4), which requires issuance of a patent not later than four months after the date on which the issue fee was paid under 35 USC 151 and all outstanding requirements were satisfied. As shown on the Office’s PTA Calculation Sheet (Exhibit A), the Office failed to issue a patent until May 12, 2009. Therefore, Patentees are entitled to a period of patent term adjustment beginning on the day after the date that is 4 months after the date on which the issue fee was paid, *i.e.*, April 20, 2009, and ending on the date the patent issued, *i.e.*, May 12, 2009. Accordingly, the period of patent term adjustment due to the 4-Month Delay by the Office is **23 days**, which is in agreement with the period calculated by the USPTO on the PTA Calculation Sheet (Exhibit A).

(iv) Calculation of Total Period of Examination Delay Pursuant to 37 CFR §1.703(f)

As set forth in 37 CFR §1.703(f), the period of examination delay based on the grounds set forth in 37 CFR §1.702 is the sum of the period of 14 Month Delay (299 days), the minimum period of Three Years Delay (380 days), and the 4 Month Issue of Patent Delay (23 days), to the extent these periods of delay are not overlapping. As the period of 14 Month Delay ended on October 18, 2005, prior to the first day of the period of Three Years Delay, *i.e.*, October 24, 2006, and the period of Three Years Delay ended on November 8, 2007, prior to the first day of the period of 4 Month Issue of Patent Delay, *i.e.*, April 20, 2009, Patentees submit that these periods are not overlapping. Accordingly, the sum of the total examination delays results in a total period of examination delay of **702 days**.

B. “Applicant Delay” Pursuant to 37 CFR §1.704

Pursuant to 37 CFR §1.704 the period of adjustment of the term of the patent due to examination delay is reduced by the period of Applicant Delay. As shown in the USPTO’s PTA Calculation Sheet (Exhibit A), the Office has calculated a period of Applicant Delay of 171 days.

(i) Applicant Delay for Filing an Information Disclosure Statement

Patentees respectfully submit that a period of Applicant Delay of **19 days** accrued for the delayed submission of an Information Disclosure Statement (IDS) on February 6, 2006. This IDS was filed without a statement under 37 CFR §1.704(d), 19 days after the filing of a response by Patentees to the Restriction Requirement on January 18, 2006. This period is consistent with the PTA Calculation Sheet (Exhibit A) from the Office. Pursuant to 37 CFR §1.704(c)(8), this 19 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(ii) Applicant Delay for Responding to Non-Final Action Dated March 16, 2006

Patentees respectfully submit that an additional period of Applicant Delay of **61 days** accrued for the delayed submission of an Amendment and Response on August 16, 2006. This is consistent with the PTA Calculation Sheet (Exhibit A) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 61 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(iii) Applicant Delay for Responding to Non-Final Action Dated November 1, 2006

Patentees respectfully submit that an additional period of Applicant Delay of **89 days** accrued for the delayed filing of a Response to Non-Final Action on May 1, 2007. This is consistent with the PTA Calculation Sheet (Exhibit A) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 89 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(iv) Applicant Delay for Responding to Notice of Allowance Dated February 25, 2008

Patentees respectfully submit that an additional period of Applicant Delay of **2 days** accrued for the delayed filing of a Request for Continued Examination and Information Disclosure Statement on May 27, 2008. This is consistent with the PTA Calculation Sheet (Exhibit A) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 2 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(iv) Calculation of the Total Period of Applicant Delay

In view of the above, Patentees have calculated a total period of Applicant Delay of **171 days**, which is the sum of the following Applicant Delays: (i) the 19 day period ; (ii) the 61 day period; (iii) the 89 day period ; and (iv) the 2 day period. Accordingly, Patentees respectfully submit that the period of Applicant Delay is **171 days**. This is consistent with the PTA Calculation Sheet (Exhibit A) from the Office.

C. Calculation of Correct Patent Term Adjustment Pursuant to 37 CFR §1.702(f)

As set forth in 37 CFR §1.703(f), Patentees are entitled to a period of patent term adjustment equal to the period of Examination Delay reduced by the period of Applicant Delay. Therefore, Patentees submit that the correct patent term adjustment for the above-referenced application is **531 days**, which is the difference between the total period of examination delay (702 days) and the period of Applicant Delay (171 days).

4. In accordance with 37 CFR § 1.705(b)(2)(iii), Patentees submit that this patent is not subject to a terminal disclaimer.

In view of the foregoing, it is respectfully requested that the accompanying Application for Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a patent term adjustment of **531 days**.

Dated: July 10, 2009

Respectfully submitted,

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